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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SARAH O'NEILL and BENJAMIN MARRERO, Plaintiffs, v. PERSON DIRECTED SUPPORTS, INC., Defendant.	Civil Action No.:_____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Sarah O'Neill and Benjamin Marrero (collectively "Plaintiffs"), by their attorneys, as for their Complaint allege on personal information as to themselves and on information and belief as to all other things the following claims against Person Directed Supports, Inc. ("Defendant"):

INTRODUCTION

1. Drugs and biologics, which include vaccines, are licensed by the Food and Drug Administration ("**FDA**"). Until these products are licensed, they are, by definition, experimental. To be licensed, manufacturers submit extensive data to the FDA from the drug's clinical trial to show it is safe and effective.

2. Nevertheless, Congress recognized the need for the FDA to authorize the use of certain experimental products in an emergency situation – even before they are shown to be safe and effective. But Congress made the policy decision that members of the public should not be forced to receive such an experimental product, instead it required that every recipient must be given the choice whether to receive that product. *See* 21 U.S.C. 360bbb-3.

3. That policy decision is why the same provision of federal law that allows the FDA to grant an emergency use authorization ("**EUA**"), expressly provides that individuals must be provided the "**option to accept or refuse** administration of" any product released under an EUA. *Id.* (emphasis added.) Until a product is approved as being safe and effective, such that it is licensed by the FDA, it remains an experimental treatment.

4. This rule ensures that the public will have confidence in the medicines they are taking, and that individuals will maintain control over their medical decisions.

5. Reflecting this principal, the FDA's guidance document regarding EUAs explains that "the statute [21 U.S.C. 360bbb-3] requires that the FDA ensure that recipients [of unlicensed experimental emergency use products] are informed … [t]hat they have the option to accept or refuse the EUA product." This rule also reflects a cornerstone of medical ethics that, for all unlicensed medical products, obtaining the uncoerced voluntary consent of the individual is essential.

6. The FDA recently granted EUAs for two vaccines against COVID-19 sold by Moderna and Pfizer (the "**COVID-19 Vaccines**"). Even though the manufacturers did submit some safety and efficacy data to obtain the EUA, the FDA's Briefing Document granting the EUA for the COVID-19 Vaccines lists the following as still **unknown**:

- "[e]ffectiveness in certain populations at high-risk of severe COVID-19,"
- "[e]ffectiveness in individuals previously infected with SARS-CoV-2,"
- "effectiveness against asymptomatic infection,"
- "effectiveness against long-term effect of COVID-19 disease,"
- "effectiveness against mortality,"
- "effectiveness against transmission of SARS-CoV-2,"
- "[a]dverse reactions that are very uncommon,"
- adverse reactions "that require longer follow-up to be detected," and
- whether the vaccines will cause "[v]accine-enhanced disease."

7. Given these outstanding issues, and in compliance with the EUA provisions, the EUAs issued by the FDA for the current COVID-19 Vaccines advise health care workers who will be administering the vaccine that "[t]he recipient or their caregiver has the **option to accept or refuse** [the] COVID-19 Vaccine[.]" (emphasis added.) The EUA further advises the public directly that "[i]t is your **choice to receive or not receive** the [] COVID-19 Vaccine." (emphasis added.)

8. The CDC, likewise, recently stated that "under an emergency use authorization," referring to the EUA issued for the COVID-19 Vaccines, the "vaccines are not allowed to be mandatory[.]" (emphasis added.) The CDC then gave the specific example of an organization like a hospital, which after full licensure could "ask[] their workers to get the [COVID-19]

vaccine[,]" but where there is only an EUA, "patients and individuals will have the right to refuse the vaccine."

9. Plaintiffs are employees at Defendant. Defendant recently announced that – in direct contravention of the EUA, FDC and CDC guidance, and federal law – it is mandating that all of its employees, including Plaintiffs, receive the COVID-19 vaccine (the "**Mandate**"). If Plaintiffs refuse, Defendant told them they will be terminated. If the Mandate is enforced, Plaintiffs will suffer harm, by being given the Hobson's choice of either being forced to take an experimental drug against their will or being fired and having their lives upended.

PARTIES AND PERSONAL JURISDICTION

10. Plaintiff Sarah O'Neill is an employee of Defendant and works in the role of Quality Assurance Coordinator at Defendant's Whitehall, Pennsylvania location. Plaintiff O'Neill has held this position for just over one year and has been with the company, formerly in other positions, for approximately four years. Plaintiff O'Neill resides in Easton, Pennsylvania.

11. Plaintiff Benjamin Marrero is an employee of Defendant and works in the role of Direct Care Staff at Defendant's Whitehall, Pennsylvania location. Plaintiff Marrero has held this role for approximately four years. Plaintiff Marrero resides in Hellertown, Pennsylvania.

12. Defendant Person Directed Supports, Inc. is, and at all times relevant herein was, an organization incorporated in Lehigh, Pennsylvania with its principal place of business in Whitehall, Pennsylvania. Defendant has two other locations in East Petersburg and Chambersburg, Pennsylvania and serves eight counties in the state of Pennsylvania. See https://www.persondirectedsupports.com/.

SUBJECT MATTER JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over the present case pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. §§ 2201. This case asserts an actual controversy arising out of Defendant's Mandate which deprives Plaintiffs of a right secured by a federal statute.

14. The venue is proper in this District under 28 U.S.C. § 1391(b) because Defendants transacted a substantial portion of their business in this District that gave rise to Plaintiffs' claim.

STATEMENT OF MATERIAL FACTS

15. Defendant Person Directed Supports, Inc. provides home-based services and support for individuals with intellectual disabilities and has approximately 450-500 employees.

16. Plaintiff Sarah O'Neill and Plaintiff Benjamin Marrero are employed by Defendant as a Quality Assurance Coordinator and Direct Care Staff, respectively.

17. Mr. Marrero previously had COVID-19 and has fully recovered.

I. Emergency Use Authorization

18. In December 2020, the FDA granted emergency use authorization for two COVID-19 vaccines. One is sold by Moderna and the other by Pfizer. Both are based on an RNA technology never before used in a licensed vaccine. The clinical trials that the FDA will rely upon to decide whether to license these vaccines are underway, but they are far from complete.

19. Before any vaccine is tested, the manufacturer is required to submit for FDA approval a clinical trial protocol, which among other things sets forth the manufacturer's estimate for how long it will take to collect adequate data to establish the vaccine is both safe and effective.

The FDA-approved study protocols for the trials for the COVID-19 Vaccines call for collecting safety and efficacy data from trial participants for approximately two years.[1]

20. Pfizer's and Moderna's COVID-19 vaccine were granted EUAs by the FDA on December 11, 2020 and December 18, 2020, respectively. When the manufacturers submitted the applications for the EUAs, they had only accumulated data from study participants for a median of 6 to 8 weeks, *i.e.*, less than 10% of the way into the full study period.

21. Given these abbreviated timelines, the EUA applications were based on data which supports that these products may reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUA authorizations made clear that there is no evidence the COVID-19 Vaccines can prevent recipients from becoming infected with and transmitting the virus. As the FDA explains, at the time of the EUA approval, the data was "not available to make a determination about how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [*i.e.*, the virus that causes COVID-19] from person to person**." (emphasis added.) Or as explained by Dr. John R. Mascola, Director of the National Institute of Allergy and Infectious Diseases' Vaccine Research Center which co-developed the Moderna vaccine: "we should appreciate that it's possible to still get exposed to the virus really from anybody whether they're vaccinated or not."[2]

22. In fact, the FDA Briefing Documents for the COVID-19 Vaccines supporting the grant of an EUA list the following as still **unknown**:

- "[e]ffectiveness in certain populations at high-risk of severe COVID-19,"
- "[e]ffectiveness in individuals previously infected with SARS-CoV-2,"

[1] Specifically, the Moderna Clinical Trial Protocol calls for 759 days of data collection and the Pfizer Clinical Trial Protocol calls for 742 days of data collection.

[2] https://www.wsj.com/articles/can-you-still-spread-covid-19-after-you-get-vaccinated-11610379107.

- "effectiveness against asymptomatic infection,"
- "effectiveness against long-term effect of COVID-19 disease,"
- "effectiveness against mortality," and
- "effectiveness against transmission of SARS-CoV-2."

23. The Briefing Documents also make clear much is **unknown** about the safety of these products, including,

- "[a]dverse reactions that are very uncommon,"
- adverse reactions "that require longer follow-up to be detected," and
- whether the vaccines will cause "[v]accine-enhanced disease."

24. As a result, the authorization letters for both COVID-19 Vaccines expressly provide that the vaccines are each "an investigational vaccine **not licensed** for any indication" and require that "**[a]ll promotional material relating to the COVID-19 Vaccine clearly and conspicuously … state that this product has not been approved or licensed by the FDA**, but has been authorized for emergency use by FDA." The authorization letters also expressly approved fact sheets for health care providers and fact sheets for patients regarding the COVID-19 Vaccines, both which provide that the receipt of either vaccine must be optional.

II. Defendant's COVID-19 Vaccine Mandate

25. On December 21, 2020, Plaintiffs and other staff received an email from Defendant's Vice President of Human Resources and Operations, Mr. Timothy Morris, stating that COVID-19 vaccines would soon be made available to Defendant and that Defendant is "making the vaccine mandatory for all employees." The email attached Defendant's "Policy and Procedure" for the Mandate which explained that:

> Dates and times will be scheduled with Walgreens for employees to go to an assigned vaccine clinic in their region to receive their vaccine.

> It is anticipated we will have little notice when this will occur. The vaccine is a two-shot vaccine…
>
> All employees are required to receive the COVID-19 vaccination…
>
> Employees choosing not to receive the COVID-19 vaccination … will have their employment separated.

26. Two days later, on December 23, 2020, Mr. Morris sent an another email on behalf of Defendant's human resources department in response to a torrent of complaints regarding the Mandate. Mr. Morris explained that the purpose of this email was "to help alleviate some peoples' concerns about the Covid vaccine" by addressing "misinformation" employees sent him about the COVID-19 Vaccines. For example, Mr. Morris indicated it was false to claim that the "vaccine was never approved to be given." However, Mr. Morris was incorrect, in reality, no COVID-19 vaccine has been approved by the FDA, and the FDA explicitly requires that promotional material for the products note that they have "**not been approved or licensed by the FDA**." (emphasis added.)

27. As another example, Mr. Morris sought to shame those that were hesitant to receive the still experimental vaccines by conflating them with those that "believe the vaccine is designed to alter DNA and turn us into fish-people." Moreover, Mr. Morris argued that such individuals were being selfish because the COVID-19 Vaccines prevent infection and transmission of the virus. But in making this assertion Mr. Morris misled his employees because there is no support for such an assertion. As noted, the FDA says there is no evidence the vaccines prevents transmission, *see supra* at II.A., and John R. Mascola, director of the federal National Institute of Allergy and Infectious Diseases' Vaccine Research Center, explained that "it's possible to still get exposed to the virus really from anybody whether they're vaccinated or not."[3] Dr. Anthony Fauci,

[3] https://www.wsj.com/articles/can-you-still-spread-covid-19-after-you-get-vaccinated-11610379107.

director of National Institute of Allergy and Infectious Diseases, has publicly stated: "We do not know if the vaccines that prevent clinical disease also prevent infection… even though you get vaccinated, we should not eliminate, at all, public health measures like wearing masks because we don't know yet what the effect [of the vaccine] is on transmissibility… We don't know that vaccinating people prevents infection… we don't know if it prevents infection."

28. The only evidence that currently exists is that these products may reduce certain symptoms in some individuals. As such, contrary to Mr. Morris' suggestion, it is entirely plausible that vaccine recipients may be infected, but not know they are infected because the vaccine reduces symptoms. Such an individual would not know to isolate him or herself, and could in fact create a greater risk of infecting others. That is why the FDA, CDC, and PA Department of Health all advise vaccine recipients to continue to wear masks, social distance, and follow all other precautionary protocols even after receiving the vaccine.

29. After Mr. Morris sent around his misleading email, Defendant's employees continued to express concerns about the company's mandatory vaccination policy. Therefore, on December 27, 2020, Emily Taylor, a nurse and Vice President of Medical Services for Defendant emailed the entire company "to help educate" them and to put their "minds at ease as we prepare for all of our staff and individuals to be vaccinated." She advised Defendant's employees that the two COVID-19 Vaccines are "[m]uch safer than any other vaccine that we have received previously," and that "the Pfizer and Moderna vaccines are [both] equally effective and safe." As noted, there is not yet any data to support this assertion, and the trials that are needed to support it are a year away from completion.

30. Even more troubling was Nurse Taylor's assertion to the employees that "[t]here are no serious adverse reactions linked to the COVID-19 vaccine." This statement is categorially

false. In the clinical trials, there were serious adverse events documented following vaccination found by the trial investigators to not only be "linked" to the vaccines, but in fact related to the vaccines. For Pfizer's vaccine, these include: shoulder injury, ventricular arrhythmia, and lymphadenopathy. For Moderna's vaccine, these include: intractable nausea and vomiting, facial swelling, rheumatoid arthritis, Dyspnea with exertion, peripheral edema, Autonomic dysfunction, and B-cell lymphocytic lymphoma. After the FDA issued the EUA, medical professionals have observed numerous serious adverse reactions linked to the COVID-19 vaccines. In fact, in the approximately one month since the EUA was issued, the CDC's Vaccine Adverse Events Reporting System, which captures "fewer than 1% of vaccine adverse events", has already received reports of the following serious adverse reactions: 66 deaths, 225 hospitalizations, and 1,386 emergency room visits following receipt of the COVID-19 Vaccines.

31. Nurse Taylor then continued her string of specious claims by declaring that "natural immunity (or antibodies formed after having COVID) does not last long after infection." The problem with this declaration is that the weight of scientific evidence falls heavily against it. Peer-reviewed studies have shown that T cell and memory-B cell immunity following infection is persistent.[4] This is why despite more than 23 million confirmed cases[5] of the virus in the United States, and a massive nationwide scientific effort to identify cases of reinfection, there are only three suspected cases of reinfection (and no cases of suspected transmission from any of these suspected cases).[6]

[4] *See Antibody Responses 8 Months after Asymptomatic or Mild SARS-CoV-2 Infection* at https://science.sciencemag.org/content/early/2021/01/06/science.abf4063.full; *see also Antibody Responses 8 Months after Asymptomatic or Mild SARS-CoV-2 Infection* at https://wwwnc.cdc.gov/eid/article/27/3/20-4543_article.

[5] *See* https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

[6] *See* https://bnonews.com/index.php/2020/08/covid-19-reinfection-tracker/.

32. Even with the grandiose, but ultimately false, assertions made in Nurse Taylor's email, Defendants' employees persisted in questioning the wisdom of its mandatory vaccination policy.

33. In another attempt to bring relucent employees into line, Defendant held three webinars regarding the COVID-19 vaccine, one on December 31, 2020, on January 8, 2021, and on January 14, 2021.

34. During the January 8th webinar presented by Nurse Taylor, Plaintiff Marrero pointed out that there is no data to show that the vaccines stop infection or transmission of the virus. Nurse Taylor replied that she knows that, but she proceeded to nonsensically claim that she made her comments regarding transmission because she "wants…to help the world population reach herd immunity." During the webinar, Plaintiff Marrero also inquired as to whether Defendant could legally mandate vaccinations because the COVID-19 vaccines are not FDA approved. Nurse Taylor ignored this question. Instead, regardless of the employees' concerns, she reiterated the Defendant's mandate that any employee who does not consent to receive vaccine will be terminated.

35. During the January 14th webinar, Defendant brought in Doctor Anthony Wehbe from an outside company, Senacare, to speak to the employees. In response to Nurse Taylor, this doctor assured employees, multiple times, that both the Moderna and Pfizer vaccine were "approved" by the FDA. Nurse Taylor then told Defendant's employees how spreading misinformation helps no one and instead causes problems. The irony in this statement is that it is Dr. Wehbe and Nurse Taylor who are misinformed and are unfortunately spreading misinformation because the two COVID-19 Vaccines are unquestionably not "approved" by the FDA.

36. Plaintiffs have not consented to receive the COVID-19 vaccine. Among other reasons, the vaccines are still undergoing clinical trials, are not yet approved or licensed for use, and have not been shown to prevent infection or transmission. Plaintiff Marrero has also already been infected with the virus and there is no data to show that he can be reinfected and transmit the virus to anyone.

III. Federal Law Prohibits Mandating Products Granted EUA

37. The same section that authorizes the FDA to grant an EUA, Section 564 of the Federal Food, Drug, and Cosmetic Act (the "**Act**"), codified at 21 U.S.C. 360bbb-3, requires that the public have "the option to accept or refuse administration of the product." 21 U.S.C. 360bbb-3(e). It even provides that the Secretary of HHS is to "ensure that individuals to whom the product is administered are informed" of "the option to accept or refuse administration of the product." *Id.*

38. The FDA and CDC's guidance and regulations reflect the statutory prohibition from mandating that an individual receive a product that has only been granted EUA. For example, the FDA guidance entitled *Emergency Use Authorization of Medical Products and Related Authorities* provides that:

> …section 564 does provide EUA conditions to ensure that recipients are informed about the MCM [medical countermeasure] they receive under an EUA. For an unapproved product [such as the COVID-19 vaccines], the statute requires that **FDA ensure that recipients are informed** to the extent practicable given the applicable circumstances … **That they have the option to accept or refuse the EUA product**…

(emphasis added).

39. Similarly, when responding to an inquiry regarding whether the COVID-19 Vaccines can be required, the Executive Secretary of the CDC's Advisory Committee on Immunization Practices ("**ACIP**"), Dr. Amada Cohen, publicly stated that under an **"EUA,**

vaccines are not allowed to be mandatory. So, early in this vaccination phase, **individuals will have to be consented and they won't be able to be mandatory**." Dr. Cohen then reaffirmed to the FDA's Vaccine and Related Biological Products Advisory Committee that no organization, public or private – including hospitals – can mandate the COVID-19 Vaccines:

> Organizations, such as hospitals, with licensed products do have capability of asking their workers to get the vaccine. But in the setting of an EUA, patients and individuals will have the right to refuse the vaccine.

40. As evidence of the importance Congress placed on an individual's right to refuse an EUA product, it carved out only one exception when a product granted an EUA *can* be required: when the President of the United States orders members of the armed forces to receive that product. 10 U.S.C. § 1107a. The President has not made such an order regarding the COVID-19 Vaccines,[7] and even if he did, Plaintiffs are not members of the military and so this sole exception is not applicable to this matter.

IV. The EUAs for the COVID-19 Vaccines Repeats this Prohibition

41. Both Pfizer and Moderna's EUA letters provide that each

> COVID-19 Vaccine is authorized for emergency use with the following product specific information required to be made available to the vaccination providers and recipients, respectively (referred to as 'authorized labeling'):
>
> - Fact Sheet for Health Care Providers Administering Vaccine
>
> … [and]
>
> - Fact Sheet for Recipients and Caregivers.

[7] Pentagon: Troops Won't Be Required to Take Coronavirus Vaccine, U.S. News & World Report (Dec. 9, 2020) *available at* https://www.usnews.com/news/national-news/articles/2020-12-09/pentagon-troops-wont-be-required-to-take-coronavirus-vaccine.

42. These facts sheets both provide that the receipt of the vaccine must be optional. The Fact Sheets for Healthcare Providers for both COVID-19 vaccines state that: "The recipient or their caregiver has the option to accept or refuse [the] COVID-19 Vaccine." Similarly, the Fact Sheets for Recipients and Caregivers for both COVID-19 vaccines state on the first page: "**It is your choice to receive the [] COVID-19 Vaccine**."

43. The Fact Sheet for Recipients and Caregivers for both COVID-19 Vaccines also set forth in sequence the information required to be provided to recipients of the vaccine pursuant to section 564 of the Act. That section requires that every individual receiving an EUA product must be informed that:

- "that the Secretary has authorized the emergency use of the product";
- "the significant known and potential benefits and risks of such use";
- "the extent to which such benefits and risks are unknown";
- "the option to accept or refuse administration of the product";
- "the consequences, if any, of refusing administration of the product"; and
- "the alternatives to the product that are available and of their benefits and risks."

21 U.S.C. 360bbb-3(e)(1)(A)(ii).

44. Both COVID-19 Vaccine Fact Sheets provide the relevant information to satisfy each of these requirements in sequence. The Fact Sheets clearly tell potential recipients: "It is your choice to receive or not receive the [Pfizer/Moderna] COVID-19 Vaccine[,]" and that if "you decide to not receive it, it will not change your standard of medical care."

V. Defendant's Vaccine Mandate Violates Both the Act and the EUA

45. By implementing its vaccine mandate, Defendant is attempting to coerce all of its employees into receiving one of the COVID-19 Vaccines. It is deliberately taking away each

employee's statutorily guaranteed right to decide for him or herself whether to accept or refuse administration of the COVID-19 Vaccines. Defendant is doing so openly, without any regard for the personal medical decisions of its employees. Worse still, it is attempting to justify its policy to its employees by using false and misleading information, presented through supposedly trustworthy medical sources like Nurse Taylor and the doctor from Senacare.

46. However, as the CDC's Executive Secretary stated, not even a hospital has the right to mandate that its employees receive one of these vaccines. If a hospital cannot implement such a mandate, there can be no doubt that Defendant cannot either. Defendant's policy of coercion through the threat of termination is therefore clearly in direct contradiction to the Act and is unlawful.

VI. Plaintiffs Will Suffer Harm

47. Plaintiffs will suffer harm if Defendant's mandate is enforced. Plaintiffs will be left with the Hobson's choice to either: (a) be forced, in violation of federal law and against their will, to be injected with an unlicensed, experimental vaccine; or (b) be terminated from their jobs during one of the worst recessions of the last hundred years.

48. A vaccine injection is a prototypical irreparable harm because it cannot be undone, nor can money compensate for the resulting harm.

49. On the other hand, Defendant has made clear that any employee that does not receive the vaccine will be terminated. The requirement to receive an experimental vaccine is a direct violation of their statutory right under Section 506 of the Act and hence constitutes harm.

50. Without a job and source of income, Plaintiffs will be unable to support themselves. Plaintiff Marrero would be unable to support his wife and children. He would not be able to pay his mortgage, credit card bills, nor an outstanding consolidated bank loan. In addition to potential

foreclosure on his home, inability to purchase basic necessities, and irreparable harm to his credit, his loss of income would prevent him from being able to pay for critical out-patient therapy for his disabled son, likely resulting in regression. Plaintiff Marrero would be unable to feed his family, including his disabled son's special diet which helps keep his sensory issues to a minimum. Plaintiff Marrero would be unable to afford health insurance for himself and his family as well.

51. Plaintiff O'Neill would be unable to pay her rent and may lose her residence. She would also be unable to pay her car loan or insurance. Plaintiff O'Neill would lose her health insurance and not be able to afford to cover the cost of any emergency, medical or otherwise.

52. Given the state of the job market for their positions in their region due to the COVID-19 pandemic, they are unlikely to find alternative work, certainly not for a significant duration of time.

53. In addition to the foregoing harms, losing one's job during regular times, let alone during one of the worst peacetime recessions in 100 years, has also been shown to be "clearly traumatic" and "can have spillover effects into one's life at home." The subsequent search for a new job also poses a risk: "research has shown that the job search process itself can result in decreased psychological well-being."

54. Plaintiff Marrero would suffer stress and emotional harm as a result of being terminated and forced to try to find alternate employment in the current state of the workforce and economy. The loss of his job and the resulting harms would additionally cause stress on his marriage and on his wife. A feeling of hopelessness would persist until he was able to obtain another job, one that would not mandate the same product.

55. Plaintiff O'Neill would suffer from increased anxiety of the unknown and continued deprivation of sleep (which she has been experiencing since the Mandate was

announced) if she were to lose her job and her health insurance. Her overall stress has adversely affected her on a daily basis since the Mandate and this would only be exacerbated upon termination from her job.

56. Defendants, on the other hand will not be harmed if its Mandate is enjoined. Defendants are free to strongly encourage, recommend, and assist their employees to receive the COVID-19 vaccine. However, these products have not been shown to prevent the vaccine recipient from becoming infected with and transmitting the virus that causes COVID-19, and for this reason, everyone working for Defendant, whether they have had the vaccine or not, must continue with all of the same precautions for avoiding contracting and spreading the virus.

VII. A Mandate for an Experimental Product Does Not Serve The Public Interest

57. Congress already decided in the Act that the public interest is best served by allowing individuals to make their own medical decisions. Congress could have allowed companies like Defendant to mandate EUA products, instead it chose to explicitly require that every individual must be allowed to freely choose whether to be injected with an experimental EUA product, like the COVID-19 Vaccines. *See* 21 U.S.C. 360bbb-3. Not only that, but even during this pandemic, the FDA and CDC guidance related to the COVID-19 Vaccines reinforced that policy decision to allow individuals to make their own decisions.

58. In light of these clear policy decisions made at the highest levels of the government, the public interest in this case will be best served by not permitting Defendant to blatantly violate the federal law intended to protect the individual's right to choose. Whether the COVID-19 Vaccines are actually safe and effective is not yet known and will not be until their Phase III clinical trials are completed. The FDA-approved study protocols for the Modern and Pfizer

COVID-19 vaccines state that those trials will not conclude for approximately another year or more.

COUNT I
DEPRIVATION OF RIGHTS AND PRIVILEGES SECURED BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT § 564

59. Plaintiffs restate and reallege paragraphs 1-58 of this Complaint and incorporate them herein by reference.

60. By mandating all employees to be injected with an unlicensed and unapproved experimental COVID-19 vaccine, Defendant is impermissibly ignoring the required condition under federal law that individuals be informed of and have the right to exercise their choice to accept or refuse a product authorized for emergency use as provided in the Food, Drug, and Cosmetic Act, § 564 codified at 21 U.S.C. §360bbb-3 which provides the exclusive and comprehensive statutory scheme for the use of produces granted emergency use authorization.

61. Plaintiffs are entitled to a preliminary and permanent injunction enjoining Defendant from implementing and enforcing its COVID-19 Vaccines Mandate because that Mandate deprives Plaintiffs of their rights secured by federal statute as alleged herein.

COUNT II
DECLARATORY JUDGMENT; UNENFORCEABLE MANDATE

62. Plaintiffs restate and reallege paragraphs 1-61 of this Complaint and incorporate them herein by reference.

63. As set forth herein, Defendant's COVID-19 Vaccines Mandate is unenforceable since it requires Plaintiffs to be injected with this unlicensed and unapproved experimental product in violation of Plaintiffs right pursuant to the Food, Drug, and Cosmetic Act, § 564 codified at 21 U.S.C. §360bbb-3 which prohibits such a requirement.

64. An actual controversy exists between Plaintiffs and Defendant with respect to whether the COVID-19 Mandate deprives Plaintiffs of a right secured by federal law to not be required to receive an unlicensed and unapproved product.

65. Declaratory relief from this Court will terminate the dispute and controversy between Plaintiffs and Defendant with respect to the enforceability and legality of the CoVID-19 Vaccines Mandate.

66. Therefore, Plaintiffs ask this Court to issue a judicial declaration declaring that the Mandate is illegal and unenforceable under relevant Federal law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the Court to enter Judgment against Defendant Person Directed Supports, Inc. as follows:

1. A declaration that Defendant's Mandate is illegal and unenforceable under Federal law;
2. An order enjoining Defendant from implementing and enforcing its Mandate as set forth in this Complaint;
3. An award for Plaintiffs' reasonable attorney fees, costs and expenses; and
4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury.

Dated: January 22, 2021

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